

I. Priority

Applicants acknowledge acceptance of their claim to the benefit of U.S. Provisional Application 60/130,992. Applicants again submit a request for a corrected filing receipt to reflect the proper reference to the priority application.

A. New Matter Objection and Rejection

The Office maintains its objection to the Amendment to the specification filed October 19, 2004, under 35 U.S.C. § 132 for introducing new matter because the Amendment incorporated by reference the disclosure of 60/132,992. Applicants respectfully submit that the incorporation by reference of the copending Provisional Application does not constitute new matter, and respectfully request that the Office withdraw this objection.

"[A]n applicant should be permitted to incorporate the disclosure of a copending application ... so long as the reference application is sufficiently well identified to distinguish it from all others." *In re Fouche*, 439 F.2d 1237, 1239 (C.C.P.A. 1971). In *Fouche*, an application was originally filed containing the phrase "prepared as described in Example I of our application No." *Id.* at 1087. After subsequent prosecution, Applicants amended the specification to change "our application No." to "my Application Serial No. 459,921 filed May 18, 1965." *Id.* The Court of Customs and Patent Appeals held that the original language in the specification was specific enough to infer an incorporation by reference to the later added Application, and thus "there can of course be no 'new matter' problems." *Id.* at 1088.

Similarly, Applicants originally filed an application with the phrase "[t]he present application claims the benefit of U.S. provisional application Serial No. 60/008660, filed on April 26, 1999 which is incorporated by reference herein in its entirety." (emphasis

added). After the Examiner noticed the obvious error in the Application No., the specification was amended to change the Serial No. to 60/132,992. Applicants submit that the reference application is “sufficiently well identified [in the original specification filed] to distinguish it from all others,” by virtue of at least the filing date, thus the amendment to incorporate the correct provisional application by reference is not new matter. If one were to identify a provisional application filed on the date of April 26, 1999, which contained the same inventors and title as the present application, one would only find provisional Application No. 60/132,992. Moreover, “it would be unreasonable to read the referring language as pertaining to anything but [a] concurrently filed United States application.” 58 C.C.P.A. at 1089. Thus the present application is “sufficiently well identified” under *Fouche* such that the amendment to correct the obvious omission should not be construed as adding new matter.

Claims 61, 64, 67, 68, 77, 78, 87, 89, 96, 102, 108, 110, and 133-138 stand rejected under 35 U.S.C. § 112, first paragraph as containing new matter. Office Action, pages 6-8. Applicants respectfully traverse this rejection on the grounds that at least the incorporation by reference of U.S. provisional application Serial No. 60/132,992, as discussed *supra*, provides adequate support for claims 61, 64, 67, 68, 77, 78, 87, 89, 96, 102, 108, 110, and 133-138.

In view of these remarks, Applicants request reconsideration and withdrawal of the new matter objection and rejection.

II. Rejection under 35 U.S.C. § 101

Claims 44-49, 52-56, 133-138, and 143 stand rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter. Office Action, pages 4-6. The Examiner states that the claims “are rejected because said claims are directed to a computer

system, memory for storing data, and data base, comprising steps for correlating data without any physical alteration step, which is considered to be non-statutory subject matter." Office Action pages 4-5. The Examiner further asserts that the "limitations have been reasonably construed as routine computer processing of data ... without any transformation." Office Action, page 6. The Examiner appears to allege that in order to be statutory, the claimed processes must transform the data somehow in a "physical alteration step."

"When a computer program is recited in conjunction with a physical structure, such as a computer memory, Office personnel should treat the claim as a product claim." M.P.E.P. § 2106 IV(1)(a). Accordingly, the test for determining whether computer related inventions have utility under 35 U.S.C. § 101, is not necessarily whether there is a "physical alteration step" as alleged by the Examiner. Rather:

"[t]here is always some form of physical transformation within a computer because a computer acts on signals and transforms them during its operation and changes the state of its components during the execution of a process. Even though such a physical transformation occurs within a computer, such activity is not determinative of whether the process is statutory because such transformation alone does not distinguish a statutory computer process from a non-statutory computer process. What is determinative is not how the computer performs the process, but what the computer does to achieve a practical application ... [f]or such subject matter to be statutory, the claimed process must be limited to a *practical application of the abstract idea or mathematical algorithm in the technological arts.*"

M.P.E.P. § 2106 IV(2)(b)(ii) (internal citations omitted)
(emphasis added).

Applicants respectfully submit that based on the above-stated M.P.E.P. test, claims 44-49, 52-56, 133-138, and 143 recite combinations including processes executed by a processor that may, for example, allow the rapid analysis of new

compounds based on data of known compounds and molecular targets, and the known interactions of the compounds and molecular targets maintained in a data structure. See Applicants' specification at e.g., page 9. The claimed combinations thereby achieve a practical application in the art, and thus have utility. Therefore, contrary to the Examiner's assertion, the claimed combinations are directed to statutory subject matter.

For example, claim 44 recites a combination including, "reflecting a relationship between a chemical compound in the first set, a molecular target included in the second set, and the information included in the third set, and wherein the information reflecting the relationship is relevant to a predictability of a potential use of a new compound." The relationship that is reflected between the compound in the first set, the molecular target in the second set, and the information in the third set, is used to analyze the potential use of a new compound, thereby providing rapid analysis of the new compound, which may, for example, aid in new drug discovery. Thus, the claimed combination achieves a practical application.

Claim 45 recites a combination including "produc[ing] information corresponding to a drug potential for a new compound based on relationships between characteristics associated with the new compound and a selected biological activity included in the fourth array of records or patterns of binding capabilities included in the third array." Applicants respectfully submit that the process of the claimed combination, by "produc[ing] information" that corresponds to a "drug potential for a new compound" based on information contained in the arrays, provides rapid analysis to data relevant in

new drug discovery. Thus, the claimed combination achieves a practical application in the art.

Claim 46 recites a combination including, “wherein the process determines information reflecting a relationship between the data included in the compound, target, and result data structures, and wherein the information reflecting the relationship is used to validate disease relevance or biological function of a new molecular target.” The process of the claimed combination determines information correlating to a specific relationship between data included in the data structures, and the information “is used to validate disease relevance or biological function of a new molecular target,” thus achieving a practical application in the art.

Claim 54 recites a combination including “creating a full-rank data set of test results.” The process, in creating the ranked data set, not only achieves a practical application in the art, but also transforms the data contained in the data sets into a ranked data set. Thus, even by the Examiner’s own test, claim 54 is directed to statutory subject matter.

Claim 133 recites a combination including, “provid[ing] selected result information based on a request associated with a selected chemical compound or molecular target.” The practical application that may be achieved by this claimed combination is “provid[ing] selected result information” which corresponds to a request made by a user that is associated with a selected chemical compound or molecular target maintained in the data structure.

Furthermore, claim 143 recites a combination including “wherein the information reflecting the relationship is used to validate disease relevance or biological function of

a new molecular target." The practical application "validat[ing] disease relevance or biological function of a new molecular target" may be achieved using the process of the claimed invention.

Claims 47-49, 52-53, 55-56, and 134-138 are also rejected under 35 U.S.C. § 101, due to their dependence on similarly rejected independent claims. Because independent claims 44-46, 54 and 133 are statutory for the reasons set forth above, Applicants submit that dependent claims 41-43, 47-49, 52-53, 55-56 and 134-138 are also statutory.

In view of these remarks, Applicants request reconsideration and withdrawal of the rejections.

III. Rejection under 35 U.S.C. § 102(b)

Claims 54-56 are rejected under 35 U.S.C. § 102(b) as being anticipated by Gschwend *et al.*, "Molecular Docking Towards Drug Discovery," Journal of Molecular recognition, vol. 9, pages 175-186, 1996 ("Gschwend"). Office Action, pages 8-9. Applicants respectfully traverse this rejection on the ground that Gschwend fails to teach each and every element of the claims.

A rejection under § 102 is proper only when the claimed subject matter is identically described, expressly or inherently, in a single prior art reference. M.P.E.P. § 2131. Moreover, in order to anticipate the claimed invention, a reference must clearly and unequivocally disclose the claimed combination to one of ordinary skill in the art "without any need for picking, choosing and combining various disclosures." *In re Arkley*, 455 F.2d 586, 587 (C.C.P.A. 1972). Importantly, missing elements may not be supplied by the knowledge of one skilled in the art or the disclosure of another

reference. See *Structural Rubber Prods. Co. v. Park Rubber Co.*, 223 U.S.P.Q. 1264, 1271 (Fed. Cir. 1984).

Claim 54 recites the combination “a data set including information corresponding to results of screening assay tests that measure an interaction between *all possible combinations* of chemical compounds in a compound set and molecular targets in a molecular target set, thereby creating a full-rank data set of test results.” (Emphasis added). Gschwend fails to teach at least this element. Thus the claim is not anticipated by Gschwend.

Gschwend teaches the use of the DOCK suite of programs, designed “to identify putative ligands complementary to a receptor of known 3D structure.” Gschwend, page 178, left column. Using the suite of programs, forty structurally distinct compounds were assayed for activity against *P. carinii* DHFR, to measure the compound’s inhibition. *Id.* page 178, right column. The seven most potent compounds against *P. carinii* DHFR are further assayed against human DHFR for specificity. *Id.*

The Examiner alleges that the forty compounds constitute a compound set, and that the *P. carinii* DHFR and the human DHFR constitute a molecular target set. However, only a small percentage of the compounds in the alleged compound set are assayed to measure an interaction with the alleged molecular target set. Since not all of the compounds in the alleged compound set are assayed to measure an interaction with all of the molecular targets in the alleged molecular target set, Gschwend fails to teach at least the element “a data set including information corresponding to results of screening assay tests that measure an interaction between *all possible combinations*

of chemical compounds in a compound set and molecular targets in a molecular target set, thereby creating a full-rank data set of test results," as recited in claim 54.

Thus, for at least that reason, Gschwend fails to teach each and every element of claim 54. Gschwend, therefore cannot anticipate claim 54. Accordingly, the Office should withdraw the rejection of claim 54 under 35 U.S.C. § 102(b).

Claims 55-56 depend from claim 54. Since Gschwend fails to teach each and every element of claim 54, that reference also fails to teach each and every element of the dependent claims. Hence the Office should withdraw the rejection of claims 55-56 under 35 U.S.C. § 102(b).

IV. Rejections under 35 U.S.C. § 103(a)

A. Goto taken with Antman

Claims 1-3, 10, 14-23, 27-28, 33-53, 59-64, 70-76, 78, 80, 89-91, 93-94, 97-105, 120, 121, 124-125, 127-129, and 132-143 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Goto, "LIGAND: chemical database for enzyme reactions," Bioinformatics, Vol. 14, no. 7, 1998, pages 591-599 ("Goto") taken with Antman, "A comparison of results of meta-analyses of randomized control trials and recommendations of clinical experts. Treatments for myocardial infarction," Journal of the American Medical Association, Vol. 268, No. 2, July 8, 1992, pages, ("Antman"). Office Action, pages 9-22. Applicants respectfully traverse this rejection on the ground that a *prima facie* case of obviousness has not been established.

To establish a *prima facie* case of obviousness under 35 U.S.C. §103(a), each of three requirements must be met. First, the reference or references, taken alone or combined, must teach or suggest each and every element recited in the claims. M.P.E.P. §2143.03. Second, there must be some suggestion or motivation, either in the

references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine the references in a manner resulting in the claimed invention. Third, a reasonable expectation of success must exist. Moreover, each of the three requirements must “be found in the prior art, and not be based on applicant’s disclosure.” M.P.E.P. § 2143. At a minimum, the Examiner cannot establish that the cited references teach or suggest each and every element recited in the claims or that a motivation exists to achieve the claimed combination.

1. Claims 1-3, 10, 14-23, 33, 34, 37-43, and 133-141

Claim 1 recites “a third database containing records corresponding to screening results from tests of interactions between **each** of a plurality of compounds in the first database and **each** of a plurality of molecular targets in the second database” (emphasis added). Goto in combination with Antman fails to teach or suggest this element. Thus, the claim is not *prima facie* obvious over these combined references.

Goto teaches the LIGAND chemical database, which includes two sections: ENZYME and COMPOUND (page 591, left col.). The COMPOUND section has information on the nomenclature and chemical structures of compounds (page 591, left col.). The ENZYME section of the LIGAND database accumulates information on known enzymes and reactions (page 592, right col.). Reaction data is reflected in the REACTION field of the ENZYME entry (page 592, right col.). Enzymatic or non-enzymatic reactions may be written in the form of a chemical reaction in the REACTION field and maintained in a relational database as a substrate-product binary relationship, or a set of substrate-product binary relationships (page 594, left col.). Goto also discloses a database called BRITE that is for molecular interactions in general

(page 597, right col.). LIGAND is a component of the KEGG and DBGET/LinkDB systems. KEGG and affiliated databases discussed in Goto are designed to incorporate individual components of natural biological systems in order to define cellular pathways present in nature.

The Examiner alleges that Goto discloses it is possible to generate all possible paths for all compounds. Office Action, pages 15-16. The purpose of the components of KEGG is to delineate natural pathways of interconnected enzymes. In such a cyclic pathway, one chemical compound interacts with both the preceding (as product) and succeeding enzyme (as substrate) or target in the pathway. Eventually, the cycle is completed by the “last” product in the pathway acting as the substrate for the “first” enzyme in the pathway. In this regard, it does represent an interaction between one chemical and each of a plurality (two) of targets. KEGG, which the Examiner has arguably characterized as “the third database” (Office Action, page 15), does not contain records that correspond to tests of interactions between **each** of a plurality of the compounds contained in COMPOUND, arguably characterized as the first database (Office Action, page 14), and **each** of a plurality of the enzymes contained in ENZYME, arguably characterized as the second database (Office Action, page 15). Accordingly, Goto fails to teach or suggest at least the element, “a third database containing records corresponding to screening results from tests of interactions between **each** of a plurality of compounds in the first database and **each** of a plurality of molecular targets in the second database,” as recited in claim 1 (emphasis added).

Moreover, Goto fails to teach or suggest “a third database containing records corresponding to screening results from tests … the tests including information on the

effect that a compound selected from the first database has on the interaction between a reference compound known to interact with a selected molecular target from the second database and the selected molecular target,” as recited in claim 1. Goto teaches interaction information in general, but not information on the effect that a selected compound has on an interaction between a reference compound and a selected molecular target.

Furthermore, Goto fails to teach “a third database containing records corresponding to *screening results from tests*” as recited in claim 1 (emphasis added). The Examiner has continued to incorrectly interpret the term “screen results” or “screening results.” The Examiner states: “Goto identifies new chemical compounds (screen results) appearing in these reactions and [adds] them as new COMPOUND entries.” Office Action, page 16. Consistent with the Examiner’s stated characterization of Goto, identifying a new chemical compound corresponds to “screening results,” and these results are subsequently added as a entry in COMPOUND, which the Examiner has characterized as the first database. According to the Examiner’s own statement, the alleged “screen results” are stored in the alleged “first database.” Even if the Examiner’s characterization of Goto was accurate, Goto fails to teach “a *third* database containing records corresponding to screening results from tests,” as recited in claim 1 (emphasis added).

The Examiner’s characterization of Goto, however, does not correctly correspond to the “screening results” of the present invention. Goto describes COMPOUND (LIGAND/COMPOUND) as a database containing “chemical compounds in living organisms (Goto page 598, Table 5), allowing natural pathways appearing in KEGG

(including via LIGAND) to be **searched** for the possible presence of such chemicals that are reported in KEGG to be components of known documented pathways.

KEGG/PATHWAY is defined as “Metabolic and regulatory pathways” (Goto, page 598, Table 5). There is no indication of any **testing** for interactions to, for example, obtain screening results. Accordingly, Goto fails to teach or suggest “a third database containing records corresponding to **screening results from tests**,” as recited in claim 1 (emphasis added).

Antman fails to cure the above-noted deficiencies of Goto. Antman, cited for allegedly teaching a first database of chemical compounds that have failed in preclinical or human clinical tests (Office Action, page 21), discusses compounds tested for their clinical effects on patients, including adverse effects. Antman does not discuss the effect of such compounds on molecular targets, only on clinical outcome. Furthermore, the compounds are tested individually on patients, so that there is no testing of the interactions of each of a plurality of compounds on each of a plurality of molecular targets. Thus, Antman fails to teach or suggest “a third database containing records corresponding to screening results from tests of interactions between each of a plurality of compounds in the first database and each of a plurality of molecular targets in the second database, the tests including information on the effect that a compound selected from the first database has on the interaction between a reference compound known to interact with a selected molecular target from the second database and said selected molecular target,” as recited in claim 1.

For at least the foregoing reasons, Goto taken with Antman fails to teach or suggest “a third database containing records corresponding to screening results from

tests of interactions between each of a plurality of compounds in the first database and each of a plurality of molecular targets in the second database, the tests including information on the effect that a compound selected from the first database has on the interaction between a reference compound known to interact with a selected molecular target from the second database and said selected molecular target," as recited in claim

1. Since the references fail to teach each and every element of claim 1, a *prima facie* case of obviousness has not been established.

Applicants further submit that the rejection is improper because Antman is non-analogous art not in the same field of endeavor as Applicants' invention, and not being rationally related to Goto. "In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." *In re Oetiker*, 977 F.2d 1443, 1446 (Fed. Cir. 1992). Antman, as discussed above, discusses compounds tested for their clinical effects on patients, including adverse effects. There is no suggestion in Antman that it could conceivably be useful in, for example, identifying interactions between compounds and molecular targets to facilitate drug discovery. Since Antman is not in Applicants' field of endeavor, nor is it reasonably pertinent to the Applicants' invention, the Office cannot rely on Antman as a reference. See M.P.E.P. §§ 2141.01(a), 2143.01 (8th ed., 2001).

For the foregoing reasons, a *prima facie* case of obviousness has not been made. Therefore, the Office should withdraw the rejection of claim 1 under 35 U.S.C. § 103(a). Because independent claims 33, 37, 133, 139, and 142 recite language similar to that which distinguishes claim 1 from Goto and Antman, Applicants further submit

that claims 33, 37, 133, 139, and 142 are patentable over Goto taken with Antman for at least the reasons given with respect to claim 1.

Claims 2-3, 10, 14-23, and 27-28 depend from claim 1. Claim 34 depends from claim 33. Claims 38-43 depend from claim 37. Claims 134-138 depend from claim 133. Claims 140-141 depend from claim 139. Since Goto taken with Antman fails to teach each and every element of claims 1, 33, 37, 133, and 139, that combination of references also fails to teach each and every element of the dependent claims. Therefore, a *prima facie* case of obviousness has not been made, and the Office should withdraw the rejection of claims 2-3, 10, 14-23, and 27-28, claim 34, claims 38-43, claims 134-138 and claims 140-141.

2. Claims 35, 36, 59-64, 70-76, 78, 80, 89-91, 93-94, 97-105, 120, 121, 124-125, and 127-129

Claim 35 recites a combination including “a third database containing data corresponding to tests of interactions between each of a plurality of compounds in the first database and each of a plurality of molecular targets in the second database.” Applicants respectfully submit that Goto in view of Antman fails to teach or suggest at least this element.

As explained above with reference to the discussion on claim 1, Goto does not include or envision a third database that includes tests of interactions between **each** of the plurality of compounds in the first database and **each** of the plurality of targets in the second database.

Accordingly, Goto does not teach or suggest “a third database containing data corresponding to tests of interactions between each of a plurality of compounds in the

first database and each of a plurality of molecular targets in the second database," as recited in claim 35.

Antman fails to cure the deficiencies of Goto. The deficiencies of Antman have been discussed, *supra*, with respect to claim 1. Accordingly, Antman fails to teach or suggest at least "a third database containing data corresponding to tests of interactions between each of a plurality of compounds in the first database and each of a plurality of molecular targets in the second database," as recited in claim 35.

Moreover, Applicants further submit that the rejection is improper because Antman is non-analogous art not in the same field of endeavor as Applicants' invention, and not being rationally related to Goto, as explained above with reference to the discussion on claim 1.

Thus, for the foregoing reasons, a *prima facie* case of obviousness has not been made. Therefore, the Office should withdraw the rejection of claim 35 under 35 U.S.C. § 103(a). Because independent claim 59 recites language similar to that which distinguishes claim 35 from Goto and Antman, Applicants further submit that claim 59 is patentable over Goto taken with Antman for at least the reasons given with respect to claim 35.

Claims 36 depends from claim 35. Claims 60-64, 70-76, 78, 80, 89-91, 93-94, 97-105, 120, 121, 124-125, and 127-129 depend from claim 59. Since Goto taken with Antman fails to teach each and every element of claims 35 and 59, that combination of references also fails to teach each and every element of the dependent claims. Therefore, a *prima facie* case of obviousness has not been made, and the Office should

withdraw the rejection of claim 36 and claims 60-64, 70-76, 78, 80, 89-91, 93-94, 97-105, 120, 121, 124-125, and 127-129.

3. Claims 44 and 143

Claim 44 recites a combination including “a third set of information reflecting interactions between each of a plurality of the chemical compounds and each of a plurality of the molecular targets … information reflecting a relationship between a chemical compound included in the first set, a molecular target included in the second set, and the information included in the third set.” Applicants respectfully submit that Goto taken with Antman fails to teach or suggest at least this element.

As explained above with reference to the discussion on claim 1, Goto does not include or envision a third database that includes tests of interactions between each of the plurality of compounds in the first database and each of the plurality of targets in the second database.

In addition, Goto fails to teach that a process may provide, based on one or more queries, information reflecting a relationship between a chemical compound included in the first set, a molecular target included in the second set, and the information included in the third set, and wherein the information reflecting the relationship is relevant to a predictability of a potential use of a new compound. Nothing in Goto provides a similar function.

Accordingly, Goto fails to teach or suggest “a third set of information reflecting interactions between each of a plurality of the chemical compounds and each of a plurality of the molecular targets … information reflecting a relationship between a

chemical compound included in the first set, a molecular target included in the second set, and the information included in the third set," as recited in claim 44.

Antman fails to cure the above-noted efficiencies of Goto. The deficiencies of Antman have been discussed, *supra*, with respect to claim 1. Accordingly, Antman is silent to "a third set of information reflecting interactions between each of a plurality of the chemical compounds and each of a plurality of the molecular targets ... information reflecting a relationship between a chemical compound included in the first set, a molecular target included in the second set, and the information included in the third set," as recited in claim 44.

Moreover, Applicants further submit that the rejection is improper because Antman is non-analogous art not in the same field of endeavor as Applicants' invention, and not being rationally related to Goto, as explained above with reference to the discussion on claim 1.

For the foregoing reasons, a *prima facie* case of obviousness has not been made. Therefore, the Office should withdraw the rejection of claim 44 under 35 U.S.C. § 103(a). Because independent claim 143 recites language similar to that which distinguishes claim 44 from Goto and Antman, Applicants further submit that claim 143 is patentable over Goto taken with Antman for at least the reasons given with respect to claim 44.

4. Claim 45

Claim 45 recites a combination including "a third array of records, each corresponding to a binding capability between each of the chemical compounds and

molecular targets.” Goto, whether taken alone, or with Antman, fails to teach or suggest at least this element.

The databases disclosed in Goto do not include an array of records, each corresponding to a binding capability between each of the chemical compounds and molecular targets. Assuming, *arguendo*, that a database in Goto can be considered to store data related to binding capability related to some chemical compounds and molecular targets, the data does not reflect a binding capability between each of the chemical compounds and molecular targets. Accordingly, Goto does not teach or suggest “a third array of records, each corresponding to a binding capability between each of the chemical compounds and molecular targets.”

Antman fails to cure the deficiencies of Goto. The deficiencies of Antman have been discussed, *supra*, with respect to claim 1. Accordingly, Antman is silent to “a third array of records, each corresponding to a binding capability between each of the chemical compounds and molecular targets,” as recited in claim 45.

Moreover, Applicants further submit that the rejection is improper because Antman is non-analogous art not in the same field of endeavor as Applicants’ invention, and not being rationally related to Goto, as explained above with reference to the discussion on claim 1.

Thus, for the foregoing reasons, a *prima facie* case of obviousness has not been made. Therefore, the Office should withdraw the rejection of claim 45 under 35 U.S.C. § 103(a).

5. Claims 46-53

Claim 46 recites a combination including “a result data structure including data corresponding to results of screening tests between each of a plurality of chemical compounds from the set of chemical compounds and each of a plurality of molecular targets from the set of molecular targets, wherein the process determines information reflecting a relationship between the data included in the compound, target, and result data structures, and wherein the information reflecting the relationship is used to validate disease relevance or biological function of a new molecular target.” Goto, whether taken alone, or in combination with Antman fails to teach or suggest at least this element.

As explained above with reference to the discussion on claim 1, Goto does not include or envision a third database that includes tests of interactions between each of the plurality of compounds in the first database and each of the plurality of targets in the second database.

In addition, Goto fails to teach that a process determines information reflecting a relationship between the data included in the compound, target, and result data structures, and wherein the information reflecting the relationship is used to validate disease relevance or biological function of a new molecular target. Nothing in Goto provides a similar function.

Accordingly, Goto fails to teach or suggest “a result data structure including data corresponding to results of screening tests between each of a plurality of chemical compounds from the set of chemical compounds and each of a plurality of molecular targets from the set of molecular targets, wherein the process determines information

reflecting a relationship between the data included in the compound, target, and result data structures, and wherein the information reflecting the relationship is used to validate disease relevance or biological function of a new molecular target," as recited in claim 46.

Antman fails to cure the deficiencies of Goto. The deficiencies of Antman have been discussed, *supra*, with respect to claim 1. Accordingly, Antman is silent to "a result data structure including data corresponding to results of screening tests between each of a plurality of chemical compounds from the set of chemical compounds and each of a plurality of molecular targets from the set of molecular targets, wherein the process determines information reflecting a relationship between the data included in the compound, target, and result data structures, and wherein the information reflecting the relationship is used to validate disease relevance or biological function of a new molecular target," as recited in claim 46.

Moreover, Applicants further submit that the rejection is improper because Antman is non-analogous art not in the same field of endeavor as Applicants' invention, and not being rationally related to Goto, as explained above with reference to the discussion on claim 1.

Thus, for the foregoing reasons, a *prima facie* case of obviousness has not been made. Therefore, the Office should withdraw the rejection of claim 46 under 35 U.S.C. § 103(a).

Claims 47-53 depend from claim 46. Since Goto taken with Antman fails to teach each and every element of claim 46, that combination of references also fails to teach each and every element of the dependent claims. Therefore, a *prima facie* case of

obviousness has not been made, and the Office should withdraw the rejection of claims 47-53.

6. Claim 132

Claim 132 recites a combination including “a third database containing records corresponding to the results of tests to determine the interaction between compounds in the first database and targets in the second database, wherein the third database includes records corresponding to the results of tests to determine the interaction between all possible combinations of the compounds selected to comprise a compound set in the first database and the molecular targets selected to comprise a molecular target set in the second database.” Goto, whether taken alone or in combination with Antman, fails to disclose at least this element.

The databases disclosed in Goto do not store information corresponding to results of screening assay tests that measure an interaction between all possible combinations of chemical compounds in a compound set and molecular targets in a molecular target set. Goto, however, does show some interaction information. For example, as noted above, the BRITE database stores information on molecular interactions in general (page 597, right col.). This information on molecular interactions, however, does not teach the concept of storing information corresponding to results of screening assay tests that measure an interaction between **all possible combinations** of chemical compounds in a compound set and molecular targets in a molecular target set.

Furthermore, Goto fails to teach “a third database containing records corresponding to the *results of tests*,” as recited in claim 132 (emphasis added). The

Examiner has continued to incorrectly use and interpret the term “screen results” or “screening results.” The Examiner states that “Goto identifies new chemical compounds (screen results) appearing in these reactions and [adds] them as new COMPOUND entries.” Office Action, page 16. Consistent with the Examiner’s stated characterization of Goto, identifying a new chemical compound corresponds to “screening results” or “the results of tests,” and these results are subsequently added as a entry in COMPOUND, which the Examiner has characterized as the first database. According to the Examiner’s own statement, the alleged “screen results” or “the results of tests” are stored in the alleged “first database.” Accordingly, even if the Examiner’s characterization of Goto was accurate, Goto fails to teach at least “a third database containing records corresponding to the results of tests” as recited in claim 132.

The Examiner’s characterization of Goto, however, does not correctly correspond to the “results of screening assay tests” of the present invention. Goto describes COMPOUND (LIGAND/COMPOUND) as a database containing “Chemical compounds in living organisms (Goto page 598, Table 5), allowing natural pathways appearing in KEGG (including via LIGAND) to be **searched** for the possible presence of such chemicals that are reported in KEGG to be components of known documented pathways. KEGG/PATHWAY is defined as “Metabolic and regulatory pathways” (Goto, page 598, Table 5). There is no indication of any **testing** for interactions to, for example, obtain screening results. Accordingly, Goto fails to teach or suggest “a third database containing records corresponding to the **results of tests** to determine the interaction between compounds in the first database and targets in the second database, wherein the third database includes records corresponding to the **results of**

tests to determine the interaction between all possible combinations of the compounds selected to comprise a compound set in the first database and the molecular targets selected to comprise a molecular target set in the second database,” as recited in claim 132 (emphasis added).

Antman fails to cure the above-noted deficiencies of Goto. The deficiencies of Antman have been discussed, *supra*, with respect to claim 1. Accordingly, Antman is silent to “a third database containing records corresponding to the results of tests to determine the interaction between compounds in the first database and targets in the second database, wherein the third database includes records corresponding to the results of tests to determine the interaction between all possible combinations of the compounds selected to comprise a compound set in the first database and the molecular targets selected to comprise a molecular target set in the second database,” as recited in claim 132.

Thus, for the foregoing reasons, a *prima facie* case of obviousness has not been made. Therefore, the Office should withdraw the rejection of claim 132 under 35 U.S.C. § 103(a).

B. Ogata taken with Antman

Claims 1, 10, 17, 59, 67, 68, 79, 81-88, 92, 95, 108, 122, 123, 144, and 145 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ogata et al., “KEGG: Kyoto Encyclopedia of Genes and Genomes,” Nucleic Acids Research, Vol. 27, No. 1, 1999, pages 29-34 (“Ogata”) taken with Antman. Office Action, pages 22-26. Applicants respectfully traverse this rejection on the grounds that a *prima facie* case of obviousness has not been established.

Independent claims 1, 59, 144, and 145 recite combinations including “a third database containing records corresponding to the results of tests to determine the interaction between each of a plurality of compounds in the first database and each of a plurality of targets in the second database.” Ogata, whether taken alone or combined with Antman, fails to teach at least this element.

Ogata teaches the Kyoto Encyclopedia of Genes and Genomes (“KEGG”), which maintains a catalog of chemical elements, compounds, and other substances in living cells as the LIGAND database (page 29, right col.). Ogata also discloses that the LIGAND database stores information of chemical compounds, enzyme molecules, and enzymatic and non-enzymatic reactions (page 33, right col.).

The databases disclosed in Ogata do not store information that reflects the effect that a compound selected from the first database has on the interaction between a reference compound known to interact with a selected molecular target from the second database and the selected molecular target. Ogata shows interaction information in general but not information on the effect that a selected compound has on an interaction between a reference compound and a selected molecular target.

As mentioned by the Examiner, Ogata is similar to Goto, in that both references discuss KEGG and other associated databases. As such, Applicants submit that Ogata fails to disclose other features of claim 1 not specifically discussed above for reasons similar to those provided with respect to Goto *supra*.

Accordingly, Ogata fails to teach or suggest at least “a third database containing records corresponding to the results of tests to determine the interaction between each

of a plurality of compounds in the first database and each of a plurality of targets in the second database," as recited in claims 1, 59, 144, and 145.

Antman fails to cure the deficiencies of Ogata for reasons similar to those provided above with respect to Goto *supra*. Moreover, for reasons similar to those provided above with respect to Goto *supra*, the rejection is improper because Antman is non-analogous art not in the same field of endeavor as Applicants' invention, and not rationally related to Ogata. Accordingly, the Office cannot rely on Antman as a reference. See M.P.E.P. §§ 2141.01(a), 2143.01 (8th ed., 2001).

Since the references fail to teach each and every element of the claimed invention, a *prima facie* case of obviousness has not been established. Accordingly, the Office should withdraw the rejection of claims 1, 59, 144, and 145 under 35 U.S.C. § 103(a).

Claims 10 and 17 depend from claim 1. Claims 67, 68, 79, 81-88, 92, 95, 108, 122, and 123 depend from claim 59. Since Ogata taken with Antman fails to teach each and every element of claims 1 and 59, that combination of references also fails to teach each and every element of the dependent claims. Therefore, a *prima facie* case of obviousness has not been made, and the Office should withdraw the rejection of claims 10 and 17 and claims 67, 68, 79, 81-88, 92, 95, 108, 122, and 123.

C. Goto taken with Antman and Witzmann

Claims 1-3, 10, 14-23, 27-28, 33-53, 59-64, 70-76, 78, 80, 89-91, 93-94, 96-105, 107, 120, 121, 124-125, 127-129, and 132-143 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Goto taken with Antman in combination with Witzmann *et al.*, "Induction of enoyl-CoA hydratase by LD50 exposure to perfluorocarboxylic acids

detected by two-dimensional electrophoresis," Toxicology Letters, Volume 71, 1994, pages 271-277("Witzmann"). Office Action, pages 27-28. Applicants respectfully traverse this rejection on the grounds that a *prima facie* case of obviousness has not been established.

The Examiner states: "Goto et al. (1998) and Antman et al. (1992) describe the limitations of claims 1-3, 10, 14-23, 27-28, 33-53, 59-64, 70-76, 78, 80, 89-91, 93-94, 97-105, 120, 121, 124-125, 127-129, and 132-143 as discussed above." Office Action, page 27. Thus, Applicants submit that Witzmann is only introduced to reject claims 96 and 107.

Claims 96 and 107, however, depend from claim 59, and thus require all of the elements of claim 59. As discussed above, Goto when taken with Antman fails to teach each and every element of claim 59. For example, Goto and Antman fail to teach or suggest at least the claimed combination including "a third database containing data corresponding to tests of interactions between each of a plurality of compounds in the first database and each of a plurality of molecular targets in the second database," as recited in claim 59.

Witzmann fails to cure these above-noted deficiencies. Witzmann, apparently cited for allegedly teaching a database comprising 2-D topological descriptors or LD50 data, teaches using electrophoresis to identify chemical induced tissue damage. Witzmann, abstract. Witzmann is silent, however, to "a third database containing data corresponding to tests of interactions between each of a plurality of compounds in the first database and each of a plurality of molecular targets in the second database," as recited in claim 59.

Since Goto taken with Antman and Witzmann fails to teach each and every element of the claims, a *prima facie* case of obviousness has not been established. Accordingly the Office should withdraw the rejections of claims 1-3, 10, 14-23, 27-28, 33-53, 59-64, 70-76, 78, 80, 89-91, 93-105, 107, 120, 121, 124-125, 126-129, and 132-143 under 35 U.S.C. § 103(a).

D. Goto taken with Antman and Schena

Claims 1-3, 10, 14-23, 27-28, 33-53, 59-64, 70-76, 78, 80, 89-91, 93-94, 97-105, 120, 121, 124-125, 126-129, and 132-143 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Goto taken with Antman in combination with Schena *et al.*, "Parallel human genome analysis: Microarray-based expression monitoring of 1000 genes," Proceedings of the National Academy of Science, Vol. 93, October 1996, pages 10614-10619 ("Schena"). Office Action, pages 28-30. Applicants respectfully traverse this rejection on the grounds that a *prima facie* case has not been established.

The Examiner states: "Goto *et al.* (1998) and Antman *et al.* (1992) describe the limitations of claims 1-3, 10, 14-23, 27-28, 33-53, 59-64, 70-76, 78, 80, 89-91, 93-94, 97-105, 120, 121, 124-125, 127-129, and 132-143 as discussed above." Office Action, page 29. Thus, Applicants submit that Schena is only introduced to reject claim 126.

Claim 126, however, depends from claim 59, and thus requires all of the elements of claim 59. As discussed above, Goto when taken with Antman fails to teach each and every element of claim 59. For example, Goto and Antman fail to teach or suggest at least the claimed combination including "a third database containing data corresponding to tests of interactions between each of a plurality of compounds in the

first database and each of a plurality of molecular targets in the second database," as recited in claim 59.

Schena fails to cure the above-noted deficiencies of Goto and Antman. Schena teaches methods for preparing microarrays for the accurate monitoring of genes. Schena is silent however to "a third database containing data corresponding to tests of interactions between each of a plurality of compounds in the first database and each of a plurality of molecular targets in the second database," as recited in claim 59.

Since Goto taken with Antman and Schena fails to teach each and every element of the claims, a *prima facie* case of obviousness has not been established. Accordingly the Office should withdraw the rejections of claims 1-3, 10, 14-23, 27-28, 33-53, 59-64, 70-76, 78, 80, 89-91, 93-94, 97-105, 120, 121, 124-125, 126-129, and 132-143 under 35 U.S.C. § 103(a).

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: June 9, 2005

By:

for Steven P. O'Connor.
Reg. No. 41,225



A handwritten signature in black ink, appearing to read "Steven P. O'Connor". To the right of the signature, the text "(Reg. No. 41,225)" is written in parentheses.